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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,662	RATNAM, MANOHAR	
	Examiner	Art Unit	
	ANNE L. HOLLERAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *10,11,18-23,28-33,38-43,48-53 and 58-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-17,24-27,34-37,44-47 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-63) in the reply filed on 1/21/2009 is acknowledged.

Applicant's election of species without traverse of steroid receptor agent that acts on glucocorticoid receptor, is acknowledged.

Claim Objections

Claims 10 and 11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 10 and 11 have not been further treated on the merits.

Claims 1-64 are pending.

Claims 18-23, 28-33, 38-43, 48-53, and 58-64, drawn to non-elected inventions, are withdrawn from consideration. Claims 10 and 11 are withdrawn as being in improper form.

Claims 1-9, 12-17, 24-27, 34-37, 44-47, and 54-57 are examined on the merits.

Claim Objections

Claim 8 is objected to because of the following informalities: typographical error ("an" is used instead of "and"). Appropriate correction is required.

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 depends from claim 8, and recites administering at least one histone deacetylase inhibitor to the patient together with one or more steroid receptor agonists or antagonists. This is not further limiting to claim 8 that requires a steroid receptor agent that comprises tamoxifen, progestin, androgens or dexamethasone. Thus, claim 9 is broader in scope than claim 8.

Claim 9 is also objected to because of the following informalities: typographical error ("deacytlase" is used instead of "deacetylase"). Appropriate correction is required

Claim 44 is objected to because of the following informalities: typographical error ("bid" is used instead of "bind"). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12, 13, 16, 17, 26, 27, 36, 37, 46, 47, 56 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is drawn to a method for diagnosing and treating a patient, while reciting only one active step of administering at least one folate receptor alpha inducer with or without one or more histone deacetylase inhibitors. The steps of claim 1 do not appear to relate to the purpose of diagnosing. Claim 1 does not state what is to be diagnosed.

Claim 3 is indefinite because no steps for the diagnostic assay are set forth.

Claim 5 is indefinite because claim 5 states that the patient is treated by administering a therapeutic agent that targets folate receptor alpha. However, claim 5 depends from claim 1, which appears to state that the patient is treated by administering at least one folate receptor alpha inducer with or without one or more histone deacetylase inhibitors.

Claim 9 is indefinite because it is not clear if the "one or more steroid receptor agonists or antagonists" refer to he listed steroid receptor agents of claim 8, or the optional "any other agent that acts on estrogen receptor (ER), progesterone receptor (PR), androgen receptor (AR) or glucocorticoid receptor (GR)."

Claims 6, 16, 26, 36, 46 and 56 are indefinite because "the steroid receptor" lacks antecedent basis in the claims, which refer to steroid receptor agents, not steroid receptors.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-8, 12-16, 24-26, 34-36, 44-46 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor (Taylor, C.W., et al. Breast Cancer Research and Treatment, 42: 7-14, 1997) as evidenced by Kelley (Kelley, K.M.M. et al. Cancer Research, 63: 2820-2828, 2003, June).

The claims are drawn to methods comprising one step of administering at least one folate receptor alpha inducer, or of using at least one folate receptor alpha inducer, wherein the folate

receptor alpha inducer is a steroid receptor agent. The elected species is a glucocorticoid receptor agent. The specification discloses that dexamethasone is a glucocorticoid receptor agent that induces folate receptor alpha. Kelley teaches that breast cancer is a cancer-type that expresses folate receptor alpha (see page 2820, left column).

Taylor teaches a method of administering a combination of cyclophosphamide, vincristine, Adiamycin and dexamethasone (CVAD) to breast cancer patients (see abstract). Therefore, Taylor teaches a method that is the same as that claimed.

Claims 1-3, 6-8, 12-16, 24-26, 34-36, 44-46 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamargo (Tamargo, R.J., et al. J. Neurosurg. 74(6): 956-961, 1991; abstract only) as evidenced by Kelley (Kelley, K.M.M. et al. Cancer Research, 63: 2820-2828, 2003, June).

The claims are drawn to methods comprising one step of administering at least one folate receptor alpha inducer, or of using at least one folate receptor alpha inducer, wherein the folate receptor alpha inducer is a steroid receptor agent. The elected species is a glucocorticoid receptor agent. The specification discloses that dexamethasone is a glucocorticoid receptor agent that induces folate receptor alpha. Kelley teaches that brain tumors expresses folate receptor alpha (see page 2820, left column). Claim 3 adds the active step of performing a diagnostic assay using samples of body fluids. However, there is no indication of what the diagnostic assay measures.

Tamargo teaches a method of administering a combination of cyclophosphamide, vincristine, Adiamycin and dexamethasone (CVAD) to Fischer 344 rats implanted with a 9L

gliosarcoma of the brain. Tamargo teaches a diagnostic test using plasma to test for concentrations of dexamethasone. Therefore, Tamargo teaches a method that is the same as that claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
April 13, 2009
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643